



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration  
158 - 15 Liberty Avenue  
Jamaica, New York 11433-1034

January 25, 2001

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

***REF: NYK-2001-39***

Stewart Berliner  
Director, Radiology  
Our Lady of Mercy Medical Center  
600 East 233<sup>rd</sup> Street  
Bronx, New York 10466

***Facility ID: #129346***

Dear Mr. Berliner:

Your facility was inspected on December 20<sup>th</sup>, 2000 by a representative of the New York City Department of Health, Bureau of Radiological Health, acting on behalf of the U. S. Food & Drug Administration (FDA). We apologize for the delay in agency review of the noncompliances during this inspection.

This inspection revealed a serious regulatory problem involving the mammography operation at your facility. Under a United States Federal Law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography procedures. The inspection revealed the following repeat Level 2 noncompliance finding at your facility:

- 1. The time period between the previous and current Medical Physicist's surveys for x-ray unit #2, Siemens Medical Systems, exceeds 14 months.***

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as a repeat Level 2 noncompliance, because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement correction of a problem found during your previous inspection.

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Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography operations at your facility, it represents a violation of the law, which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography operations.

In addition, there were also two (2) non-repeat Level 2 noncompliance findings that were listed on the inspection report provided at the close of the inspection. Those two (2) non-repeat Level 2 noncompliances were:

- 1. The Phantom QC records were missing for at least two (2) weeks but less than four (4) weeks for unit #2, Siemens Medical Systems, Room #205.*
- 2. Two (2) of ten (10) random reports reviewed did not contain an assessment category for the site.*

It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct the violations noted in this letter;*
- Each step your facility is taking to prevent the recurrence of similar violations; and*
- Sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records.*

*Please submit your response to the above issues to the attention of Arthur S. Williams, Jr., Compliance Officer, U. S. Food & Drug Administration (FDA), 158 - 15 Liberty Avenue, Jamaica, New York 11433-1034, Tel.: (718)/662-5568.*

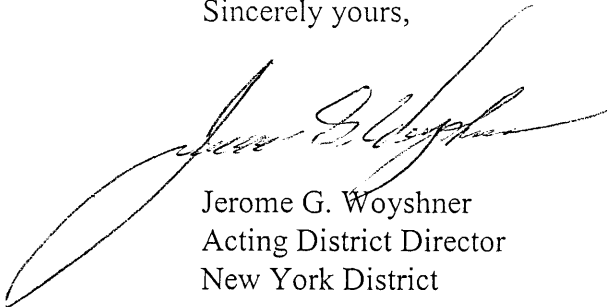
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Finally, you should understand there are many FDA requirements pertaining to mammography operations. This letter pertains only to findings of the inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food & Drug Administration, P. O. Box 6057, Columbia, Maryland 21045-6057 (1-800/838-7715), or through the Internet at <http://www.fda.gov>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jerome G. Woyshner", is written over the typed name and title.

Jerome G. Woyshner  
Acting District Director  
New York District